OTOLOGY

Cochlear implant failure: diagnosis and treatment of soft failures

Fallimento chirurgico dell'impianto cocleare: diagnosi e trattamento dei fallimenti chirurgici di lieve entità

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SUMMARY

Objective. Early diagnosis of cochlear implant failures (CIF) is a critical part of post-implantation follow-up. Diagnosis is challenging and time consuming. Our study aimed to describe diagnoses of CIF with emphasis on soft failures (SF), focusing on symptoms, time from symptoms to replacement, and differences between SF and hard failures (HF).

Methods. A retrospective review of medical records in a tertiary care referral paediatric medical centre including all patients who experienced CIF during 2000-2020.

Results. Of 1004 CI surgeries, 72 (7.2%) cases of CIF were included, of which 60 CIF were in children (mean age 3.1 years). Twenty-five cases were due to HF, 26 SF, and 21 due to medical reasons. Patients with SF were more likely to present with headache, dizziness, or tinnitus compared with those with HF. Facial stimulation and disconnections were more common in implants from Advanced Bionics, dizziness and tinnitus in Cochlear, and poor progression in Med-El. Mean time from symptoms to implant replacement surgery was longer in cases with SF compared to HF.

Conclusions. SF poses a diagnostic challenge. Symptoms such as headache, dizziness, and tinnitus are common. Diagnosis of failure should often be based on assessments of the implant and rehabilitation teams.

KEY WORDS: cochlear implant, soft failure, hard failure

RIASSUNTO

Obiettivo. La diagnosi precoce degli insuccessi dell'impianto cocleare (CIF) è una parte fondamentale del follow-up post-impianto. La diagnosi è impegnativa e richiede tempo. Il nostro studio mira a descrivere le diagnosi di CIF con focus sui fallimenti lievi (SF), i sintomi correlati, il tempo dall'insorgenza dei sintomi alla sostituzione dell'impianto e le differenze tra SF e fallimenti severi (HF).

Metodi. Revisione retrospettiva delle cartelle cliniche di un centro medico pediatrico di riferimento, relative a tutti i pazienti che hanno avuto una CIF nel periodo 2000-2020. Risultati. Su 1004 interventi chirurgici di IC, sono stati inclusi 72 (7,2%) casi di CIF, di cui 60 CIF nei bambini (età media 3,1 anni). Venticinque casi sono classificabili come HF, 26 SF e 21 iatrogeni. I pazienti con SF avevano maggiori probabilità di presentare cefalea, vertigini o acufeni rispetto a quelli con HF. La stimolazione facciale e le disconnessioni erano più comuni negli impianti con Advanced Bionics, vertigini e acufeni con Cochlear, e scarsa progressione con Med-El. Il tempo medio dai sintomi all'intervento di sostituzione dell'impianto è stato più lungo nei casi con SF rispetto all'HF.

Conclusioni. SF pone una sfida diagnostica. Sintomi come mal di testa, vertigini e tinnito sono abbastanza comuni. la diagnosi di fallimento dovrebbe spesso basarsi sulle valutazioni delle équipe implantari e riabilitative.

PAROLE CHIAVE: impianto cocleare, fallimento chirurgico lieve, fallimento chirurgico grave

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Conflict of interest

The Authors declare no conflict of interest.

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Introduction

Early diagnosis and treatment of cochlear implant failure (CIF) is crucial and challenging, especially among paediatric patients, for whom hearing plays a major role in language development. The rate of CIF varies between 4-15% among different studies ¹⁻⁸.

CIF can be divided into three major categories: hard, soft, and medical failures. In hard failure (HF), the implant malfunctions and there are abnormal findings in integrity tests. Medical failures include all medical reasons not related to electronic failure, such as infection, flap necrosis, trauma, and electrode migration. Soft failure (SF) is defined as the presence of signs and symptoms of device failure that are not supported by objective integrity tests ⁹. These symptoms improve or resolve after replacement of the implant. Since the diagnosis of SF is based on subjective complaints and lack of speech and language development, diagnosis and treatment are challenging and frequently delayed ⁸.

The aim of our study was to describe the process and challenges of CIF diagnosis in our institute, with special emphasis on SF. In a previous study from our centre, we described a small case series of CIF⁷. In the current study, we expanded the sample size and evaluated symptoms, time from symptoms to diagnosis and replacement, efficacy of the company's electronic measures to assess electronic failure, and pre-operative and post-operative lab results. A better understanding of the characteristics of CIF may lead to earlier diagnosis and treatment, especially in SF cases.

Materials and methods

Patients

A retrospective chart review was performed on all patients who underwent cochlear implantation and experiencing CIF in a tertiary care paediatric medical centre during 2000-2020. This study includes 26 patients with CIF who were already described in a previous study from our centre ⁷. Data was collected on demographics, symptoms, medical findings, radiology studies, time to appearance of symptoms and replacement surgery, integrity tests, and manufacture's device analysis reports after extraction. In our country, the patient or patient's caregiver can choose between the three manufacturers – Advanced Bionics, Cochlear and Me-del. Within a specific brand, the specific electrode model was chosen according to the presence of inner ear anomaly. The study was approved by the local institutional review board (IRB-0492-13-RMC).

Suspected failure work-up

When CIF was suspected, the work-up included history, physical examination, imaging performed in order to rule

out tip fold-over or implant migration (plain X-ray and/ or computed tomography), re-programming of the device, replacement of external hardware and integrity testing (a simulation test that examine the electrical fields in response to different electrical stimulation for each electrode contact) performed by the manufacturer. When headache was encountered, physical examination to rule out local inflammation was performed, pain management was attempted and evaluation by a neurologist was performed. Regarding dizziness and tinnitus, physical examination, neurologist evaluation and imaging were initially performed. When facial stimulation appeared, an attempt was made to map the malfunctioning electrode by inducing the stimulation and when identified it was turned off. If no improvement was demonstrated, the CI was eventually replaced.

Failure definition

HF was defined as interruption of auditory input combined with abnormal integrity test. SF was defined as patients presenting with poor progression and/or with symptoms that may suggest CIF, such as persisting headache, dizziness, tinnitus, facial stimulation, or refusal to use the device, while integrity tests were normal. Working diagnosis of implant failure was made when signs and symptoms persisted after complete work-up, as mentioned above. Final diagnosis of SF was made after re-implantation based on resolution of symptoms and/or functional improvement. However, the most accepted definition of SF includes postremoval negative hardware analysis. Our main focus was pre-operative assessment, since the decision to replace an implant is based on clinical presentation and integrity report. Thus, when SF was suspected and integrity test was normal, it was defined as SF even when the company's laboratory assessment after removal was positive, as long as symptoms resolved, and the patient regained adequate function.

Medical failures included trauma to the device area, wound infection, flap necrosis, and device or electrode migration.

Post-re-implantation assessment

The Categories of Auditory Performance (CAP), a non-linear hierarchical scale that measures supraliminal performance as an index of auditory perceptive ability in every-day life, was used to assess the audiological performance after CI replacement ¹⁰. Scores ranged from 0 (displays no awareness of environmental sounds) to 7 (can use the telephone with a familiar talker).

In addition, thorough and close assessment was performed by the CI multi-disciplinary team after replacement surgery, regardless of the suspected aetiology of CIF.

Statistical analysis

Continuous variables are presented as means ± standard deviation, and were compared between groups using the student's T test and Mann-Whitney test. Categorical variables were compared between groups using the Fisher exact test. Time to failure was calculated as months from the initial surgery to implant replacement surgery and presented using Kaplan-Meier's survival curves. The IBM SPSS Statistics for Windows, version 26.0 (IBM Corp. Armonk, NY) was used for all analyses.

Results

Descriptive data

During the study period, 1004 cochlear implant surgeries were performed at our institute. A total of 72 (7.2%) were defined as CIF in 63 patients (9 patients had 2 CIFs each), 60 failures were in paediatric patients (younger than 18 years), and 12 in adults. The mean age of paediatric failure cases at primary implantation surgery was 3.1 ± 3.1 years; mean age of adult cases at primary surgery was 44.6 ± 20.5 years. Mean time from implantation to appearance of symptoms was 34 ± 39 months, and mean time from implantation to replacement surgery was 44.1 ± 41 months.

Twenty-five (34.7%) cases were HF, 26 (36.1%) were considered SF, and 21(29.2%) were due to a medical reason. When excluding the AB vendor B model and N5 models by Advanced Bionics and Cochlear, respectively, 18 were SF (31%), 19 were hard (32.8%), and 21 were due to medical reason (36.2%).

When taking into consideration the post-removal manufacturer analysis report, of 26 SF, 11 (42.3%) had positive findings in the post-removal report (mostly hermeticity issues and electrode malfunction) although the integrity tests before surgery were normal (Tab. I).

The incidence of failure for Advanced Bionics was 28/248 (11.3%) implants (Advanced Bionics Corporation, Sylmar, CA, U.S.A), of which 8 were the AB vendor B model that was recalled in 2006. For Cochlear, 26/396 (6.6%) failed

(Cochlear Corporation, Lane Cove, Australia), of which 6 were the N5 model that was recalled in 2011, and 18/360 (5%) by Med-El (Med-El Corporation, Innsbruck, Austria).

Soft failure patients

Regarding 26 SF cases, mean age at primary implant surgery for paediatric patients was 4.6 years (19 patients), and mean age for 7 adult patients was 44.3 years. Two had large vestibular aqueduct diagnosed by pre-operative imaging. No other cochlear or labyrinthine malformations were demonstrated. One child had significant medical background of hydrocephalus treated by ventriculo-peritoneal shunt prior to CI surgery. No cases of cochlear ossification were recorded. Regarding primary CI operation, incomplete electrode insertion was described in 3 cases (11.5%). Other adverse events were reported in 8 surgeries, including cerebrospinal fluid gusher in 5 cases, and damage to the dura in 3 cases.

Symptoms at failure presentation

We reviewed the symptoms of children with SF and HF. The common symptoms in the SF sub-group included poor progression (50%), headache or local pain (38.5%), tinnitus (34.6%), dizziness (30.8%), facial stimulation (15.4%), refusal to use the speech processor (15.4%) and disconnections (11.5%); 20/26 (77%) children had more than one symptom. A comparison of symptoms between SFs and HFs showed that prevalence of headache or local pain, tinnitus and dizziness was significantly higher among cases of SF (Tab. II). We found no significant correlation between the use or refusal to use the CI and specific symptoms.

We also examined the distribution of different symptoms among the three manufacturers. In Advanced Bionics implants, facial stimulation and disconnections were more common compared to other companies. For Med-El CIF's, poor progression as a sign for failure was significantly more common compared to other companies (61.1 *vs* 33.3%, p = 0.037). In Cochlear (Nucleus) failures, dizziness and tinnitus were significantly more common symptoms. Significant and marginally significant differences in symptoms

Table I. CIF according to failure type and manufacturer.

Total	Medical	Hard failures	Soft failures (*)	Manufacturer
28	6	10	12 (7)	AB
8	0	3	5 (5)	AB vendor B
18	8	7	3 (1)	Med-El
26	7	8	11 (3)	Nucleus
6	0	3	3 (0)	N5
72	21	25	26 (11)	Total

^{*} Positive findings in post-removal report; AB: Advanced Bionics.

Table II. Comparison of symptoms at CIF presentation between soft and hard failures.

<i>p</i> -value	Hard failures (n = 25)	Soft failures (n = 26)	Symptoms
0.47	10 (40%)	13 (50%)	Poor progression
0.03	1 (4%)	10 (39%)	Headache or local pain
0.06	1 (4%)	9 (35%)	Tinnitus
0.03	0	8 (31%)	Dizziness
0.17	1 (4%)	4 (15%)	Facial stimulation
0.17	1 (4%)	4 (15%)	Refusal to use the external unit
0.14	7 (28%)	3 (12%)	Disconnections

CIF: cochlear implant failures.

presentation between the companies are presented in Table III.

Time to diagnosis and treatment

A comparison was made between SF and HF cases regarding time between primary implant surgery and appearance of failure symptoms, and the time between appearance of symptoms and replacement surgery. No significant difference was shown in the average time from primary implant surgery to symptoms in all CIF cases combined and in manufacturers' sub-group divisions.

The mean time from beginning of failure symptoms to replacement surgery was significantly longer in SFs compared to HFs (17.4 vs 7.0 months, p = 0.007). This difference was still significant when we divided CIFs into different manufacturers sub-groups (Fig. 1).

The total time from primary implant surgery to replacement was 53.6 months in SF compared to 38.2 in HF; however, this difference was not significant (p = 0.23) for the entire CIF cohort or for manufacturers' sub-groups, except for Med-El CIF (61.4 months in SF vs 21.9 months in HF, p = 0.045).

Integrity tests

In soft failures, integrity tests were defined as normal. However, in 4 cases (15.4%) one electrode was suspected as malfunctioning and was disconnected.

Manufacturer's post-removal analysis reports

In all removal surgeries, no difficulties were encountered during removal of the cochlear implant electrode from the cochlea. Regarding manufacturer's post-removal analysis reports, only for HF and SF (n = 51), the common findings included hermeticity problems (n = 18), electrode malfunction (n = 11), and other causes (n = 3). In 19 CIFs no cause for implant failure was found in the analysis. Hermeticity issues were more common among implants from Advanced Bionics, and in the AB Vendor B model specifically (7 of 8 cases, 87.5%). This trend, however, was not significant (45.5 vs 27.6% in other companies, p-value = 0.186). Electrode malfunction was significantly more likely to be discovered in Med-El CIF, as in 70% of these implants it was determined as the cause for failure, compared to 9.8% in other companies (p < 0.001). Ten of 18 Med El implants were of the Flex 28 model, 6 the Medium model, 1 the Flex 24 and information regarding one implant model

Table III. Significant and marginally significant differences in symptoms presentation among different manufacturers.

<i>p</i> -value	No. (%) of other manufacturer's CIF's	No. (%) of CIF's	Symptom	Manufacturer
0.051	1 (2%)	4 (14%)	Facial stimulation	AB
0.067	4 (9%)	7 (25%)	Disconnections	AB
0.037	18 (33%)	11 (61%)	Poor progression	Med-El
0.037	11 (20%)	0	Tinnitus	Med-El
0.083	8 (15%)	0	Dizziness	Med-El
0.037	11 (20%)	0	Disconnections	Med-El
0.015	2 (4%)	6 (23%)	Dizziness	Cochlear
0.039	4 (9%)	7 (27%)	Tinnitus	Cochlear
0.079	5 (11%)	7 (27%)	Headache	Cochlear

AB: Advanced Bonics.

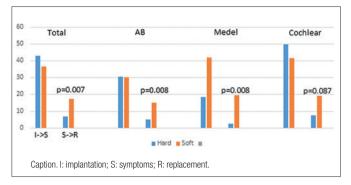


Figure 1. Mean time (in months) from primary implant to symptoms and from symptoms to implant replacement – a comparison between soft and hard failures.

was missing. No significant correlation was demonstrated between the electrode model and electrode malfunction (p = 0.36). Tip fold-over was demonstrated in pre-removal imaging in only one case.

Post re-implantation follow-up

Regarding SF, we compared the pre-replacement and post-replacement CAP scores. Data regarding CAP was available for 25 children regarding pre-replacement and for 23 children regarding post-replacement. The post-replacement CAP score was significantly higher $(4.96\ vs\ 1.12,\ p<0.001)$.

CI survival

A Kaplan-Meier survival curve of all cochlear implants performed in our institute is shown in Figure 2. The 5-, 10- and 15-year overall survival rates were 94.6, 91.% and 88.4%, respectively (Fig. 2).

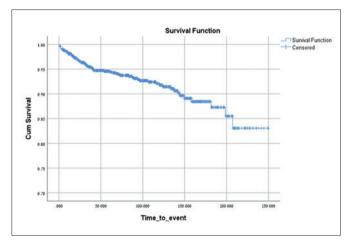


Figure 2. Kaplan-Meier survival curve for 1004 Cochlear implants.

Discussion

Our study shows that SF is a common presentation of CIF. The mean time from appearance of symptoms to implant replacement was significantly longer in SF. Certain symptoms such as dizziness, headache, local pain and vertigo were more common among SFs compared to HFs. Furthermore, some symptoms were more common in implants from specific manufacturers. These findings may assist in improving and shortening the time to diagnosis and treatment of SF.

In our study, 34.7% of CIF were HFs, 36.1% were SFs, and 29.2% were medical failure. When we excluded two recalled series (Advanced Bionics Vendor B and the Cochlear N5), the rate of SF and HR remained similar (SF - 31% and HF -32.8%), while the rate of medical failure was slightly higher (36.2%). Hence, the rates of either HF or SF presented cannot be solely related to the recalled series.

Cullen et al. ¹ reviewed CIF in 952 CI surgeries performed on paediatric patients in two centres. They described 107 (11.2%) failures with 46% HFs, 15% SFs, and 37% failures due to medical reasons. Failure due to trauma was considered as HF (20/49 HF cases). In our cohort, the rates of HF were lower as we categorised trauma as medical failure. Furthermore, our results showed a higher rate of SF. Yeung et al. ⁸ described 67 CIF of 869 cochlear implants performed in children; 30 (45.5%) failures were HF, 23 SF (34.8%) and 13 (19.7%) due to medical failure. Stevens et al. ² described rates of HF and SF in their study (37% and 31.5%, respectively). These percentages are similar to our results.

Cullen et al.'s study of paediatric patients ¹, and Stevens et al.'s ² and Buchman et al.'s ³ study of adult patients described poor progression, tinnitus, pain, dizziness and facial stimulation as frequent symptoms of SF, similar to our findings. These results emphasise the need for a low threshold of suspicion for SF when these symptoms are reported. Furthermore, data regarding the correlation between specific symptoms and manufacturers is limited. We found a correlation between manufacturers and specific symptoms, such as a higher rate of facial stimulation and disconnections in AB, poor progression in Med-El, and dizziness and tinnitus among Cochlear failures. This may promote earlier diagnosis of SF.

In our previous study by Ulanovski et al. ⁷, the cohort described was much smaller and included only 26 patients. Common symptoms and complaints in SF cases included disconnections, frequent replacement of external parts, behavioural changes, decline in auditory awareness, deterioration in sound quality and slower progression. However, no significant difference was demonstrated compared to HF, and no manufacturers' specific symptoms were described, probably due to the small sample size.

Stevens et al. ² described the mean time from appearance of symptoms to implant replacement and found that 35 months elapsed from primary implant to replacement in cases of SF, compared to 37 months in HF cases. Yeung et al. 8 reported a longer time from primary implant to replacement surgery in SF compared to HF of 70 vs 44 months. This trend was also demonstrated by Chung et al. 11 as the time to revision surgery was 4.7 years for SF, compared to 4.3 years for other failures in their cohort. However, the differences described in these studies were not compared statistically. Our data showed a time from primary implant to replacement of 53.6 months in SF and 38.2 months in HF, although this difference was not statistically significant. Since the time from symptoms appearance to implant replacement is more relevant to determine whether SF may pose a greater diagnostic challenge, we examined and demonstrated a significantly longer time from symptoms to replacement in SF compared to HF cases (17.4 vs 7 months p = 0.007). When comparing different manufacturers, this difference remained significant for Advanced Bionics and Med-El and was marginally significant for Cochlear (Nucleus) implants (Fig. 1). Ulanovsky et al. were also able to demonstrate a significant difference in the time from appearance of symptoms to replacement in SF compared to HF (17.5 vs 3 months).

The most accepted definition of SF includes both pre- and post-removal negative laboratory results findings with functional improvement and resolution of symptoms after revision surgery. In our study, we were able to demonstrate a significant improvement in performance after implant replacement among SF cases. Cullen et al. 1 reported that 75% of cases defined as SF by their pre-operative assessment had positive post-operative laboratory reports. Buchman et al. 3 described similar findings in 25% of their SF cases. These results, combined with our result of 42% positive post-removal laboratory findings in SF cases, suggest that the integrity test performed prior to removal of a malfunctioning CI can have a high false negative rate. This highlights the importance of awareness by the implant programme team, rehabilitation centre team, education centres and parents for minor functional and behavioural changes. Importantly, it also emphasises that diagnosis of device failure and decision for re-implantation is the responsibility of the implant centre. We suggest repeated mapping and assessment by the company's clinical representative, replacement of external parts, and CI examination by the manufacturer. Device functional analysis by manufacturers is an adjunct to diagnosis, but clinical assessment and data regarding functional progress by the CI team are the basis for post-operative follow-up and decision making.

Our rates of CI survival were 94.6% at 5-years post im-

plantation, 91.8% after 10 years and 88.4% after 15 years. These results show that in general, the survival of CI is high and is quite stable after 5 years, with a 3% decrement every 5 years. Similarly, Karamert et al. ⁵ reviewed 802 CI surgeries in children and adults and showed a 91.9% 10-year CI survival. Kim et al. ⁴ reviewed 925 surgeries, of whom 723 were paediatric patients, and showed a 95% 5-year survival and 94% 10-year survival.

Conclusions

SF poses a diagnostic challenge. In addition to disconnections and functional decrement, symptoms such as headache, dizziness, and tinnitus are relatively common. As SF is a relatively common presentation of device failure, due to significant false negative value of integrity tests, diagnosis of failure should often be based on assessments and findings of the implant and rehabilitation team.

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